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AWARD NUMBER DAMD17-96-1-6319

TITLE: Risk Factors for Osteoporosis and Oral Bone Loss in Postmenopausal Women

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REPORT DATE: October 1998

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. AGENCY USE ONLY *(Leave blank)*	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	October 1998	Annual (16 Sep 97 - 15 Sep 98)

4. TITLE AND SUBTITLE
Risk Factors for Osteoporosis and Oral Bone Loss in Postmenopausal Women

5. FUNDING NUMBERS
DAMD17-96-1-6319

6. AUTHOR(S)
Jean Wactawski-Wende, Ph.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
University of New York at Buffalo
Amherst, New York 14228-2567

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT *(Maximum 200 words)*

The overall purpose of this study is to determine the relationship between skeletal and oral bone density, identify factors influencing bone loss, and determine the relationship between osteoporosis and oral bone loss, periodontal disease and tooth loss. We hypothesize that reduction in bone density leading to osteoporosis, plays a significant role in increasing susceptibility to destructive periodontitis and tooth loss. Sensitive and accurate measures of skeletal and oral bone mineral density, periodontal disease and tooth loss will be used. A wide variety of other risk factors for both osteopenia and periodontal disease will be assessed. A total of 1300 subjects are being recruited from an ongoing NIH funded study cohort, the Women's Health Initiative (WHI). Preliminary research findings from our pilot study determined that bone loss in the hip or spine is strongly associated bone loss in the jaw. Also, that bone loss in the hip was associated with tooth loss even when controlling for factors such as age, menopause, estrogen use, body mass and smoking. We have just completed year two of a four year study. Data collection will continue into year-4, as such, findings are not yet available to report.

14. SUBJECT TERMS
Osteoporosis

15. NUMBER OF PA
48

16. F...

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

FOREWORD

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Jean Wactawski-Wende 10/14/98

PI - Signature Date

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INTRODUCTION

The overall purpose of this study is to determine the relationship between skeletal and oral bone density, identify factors influencing bone loss, and determine the relationship between osteoporosis and oral bone loss, periodontal disease and tooth loss. We hypothesize that reduction in bone density leading to osteoporosis, plays a significant role in increasing susceptibility to destructive periodontal disease and tooth loss.

Sensitive and accurate measures of skeletal and oral bone mineral density, periodontal disease and tooth loss are used in this study. A wide variety of other risk factors for both osteopenia and periodontal disease will be assessed as part of this study. A total of 1300 subjects are being recruited from an ongoing NIH funded study cohort, the Women's Health Initiative (WHI), making this an efficient and cost effective study.

A limited number of studies have assessed bone loss in the oral cavity and have suggested that low bone density is associated with severe periodontal disease. However, these studies have been plagued with small sample sizes and poor assessments of confounding factors such as smoking, alcohol intake, and age, among others. Our study will assess these factors in detail. Our preliminary research findings have determined that bone loss in the hip or spine is strongly associated bone loss in the jaw. Also, that bone loss in the hip was associated with tooth loss even when controlling for factors such as age, years since onset of menopause, estrogen use, body mass and cigarette smoking (1).

The U.S. population is projected to include an increasing proportion of older men and women in the next few decades, including retired and active military personnel. Hence, management of two of the most common chronic diseases in older persons, osteoporosis and periodontal disease, will demand increasing health service resources. New approaches to prevention, early diagnosis and intervention of these diseases are critical. The proposed study has great practical significance. If oral bone loss is a predictor of low skeletal bone, those people detected on a dental exam to have oral bone loss could be targeted for further evaluation for osteoporosis. Interventions could be started to prevent further bone loss or fracture. Conversely, those with weak skeletal bones may need evaluation for oral bone loss, preventing further loss of bone and subsequent tooth loss. This study potentially provides a new approach to screening for osteoporosis. Last, treatments affective for osteoporosis may prove useful in the prevention and treatment of oral bone and tooth loss.

BODY

Experimental Methods, Assumptions and Procedures:

Population to be studied. Subjects for the dental examination and dual-energy x-ray absorptiometry (DXA) are being recruited from the participants in the Women's Health Initiative. The Women's Health Initiative (WHI) is a major research effort to study methods of disease prevention and health promotion among postmenopausal women, It includes a Clinical Trial and Observational Study (OS). Only women from the OS will be recruited to join this study.

The WHI Observational Study (OS) will follow postmenopausal women aged 50-79 years who are unwilling to participate or ineligible for the CT. As part of WHI the women have many baseline measurements, with clinical outcomes determined at annual intervals. The objectives of the OS are to obtain better estimates of the predictive ability of known risk factors for disease, to unearth new risk factors and biomarkers for disease, and to examine the relationships of change in characteristics to prevalent and future disease.

In Buffalo, a total of 2248 women have enrolled into the OS. Women agreeing to participate in the Observational Study will be followed for an average of 9 years by the WHI staff. Baseline data collected as part of the OS will be related to putative risk factors and protective factors.

The current study, "Risk Factors for Osteoporosis and Oral Bone Loss", will add a bone density scan and an oral examination to the Buffalo WHI OS protocol, assess the prevalence and severity of osteopenia in this cohort of women, and evaluate osteopenia's role in development of periodontal disease/oral bone loss, and assess risk variables common or unique to each disease.

Subject recruitment. Subjects are being recruited from the WHI Observational Study participants. Subjects for the WHI OS study were assembled from community volunteers and introduced to various aspects of the WHI study. Women who are enrolled in the WHI Observational Study are contacted by mail and given information about the Osteoporosis/Oral Bone Loss study and asked to participate. A recruitment tool is the offer of a free bone density assessment and dental/oral health examination. Each woman who expresses interest in the study is initially given a brief eligibility screen. Those determined eligible are appointed for a clinical examination.

There are 2,248 women participating in OS of the WHI in Buffalo who will be eligible for the study of risk for periodontal disease in older women described here. Of this group, 1300 are expected to participate in this study. To date, recruitment into this study has been extremely successful. Details of subject recruitment as of 09/15/98 are presented in "Results and Discussion" section of this report.

Mailing. Women who have already entered the WHI OS study are contacted by mail and asked to call our center if they are interested in learning more about participating. When they call, these women are told about the osteo/dental study, given an opportunity to ask questions, and those who are interested are given a brief eligibility screen.

Eligibility Screen. Information collected on the eligibility screen concern criteria for both DXA and dental assessments. DXA scan exclusion criteria include recent use of contrast agents and known aortic calcification, steroid dependency (use of systemic steroids for the past 6 months), and active cancer or cancer chemotherapy. Criteria for the Periodontal study are that subjects

have at least 6 teeth and have had no periodontal surgery in the last 3 months. Age (50 to 79) and postmenopausal status have already been met as part of WHI. All eligible women are informed that they will be required to sign an informed consent prior to DXA and dental examinations. If women are determined to be both eligible and interested, they are scheduled for an appointment and sent a study packet by mail. The study packet includes information on temporary exclusion criteria to be aware of (i.e. contrast agents), study questionnaires to be completed at home and brought to the study visit, the consent form to read and review, instructions on what to wear and bring with them, information on premedication (if necessary), and a parking pass for the visit.

Examinations and Testing. At the time of the appointment, a DXA scan is performed by a trained and certified x-ray technician. All subjects accepted into the study receive a measurement of bone mineral density by DXA. The DXA sites will include the lumbar spine, femur and forearm, as well as a determination of whole body composition (fat, lean, mineral content). As part of the oral examination, all subjects receive a complete head and neck and intraoral examination with assessment of periodontal disease by both probing depth and assessment of alveolar crestal height. In addition, mandibular bone density is assessed using a stepwedge radiographic technique.

Before examination begins, participants are required to sign an informed consent form which is reviewed with the participant by a member of the staff. Questions are answered on risks, benefits, voluntary participation and confidentiality.

Questionnaires are self-administered and brought to the visit. At the time of the visit the questionnaires are reviewed by study personnel for completeness and accuracy. Participants can request assistance in completing the questionnaires if needed. Additional information (not collected as part of WHI) on osteoporosis risk factors, oral health history, current medication intake and personal habit history are included in the questionnaires (see Appendix).

The **DXA exam** includes: AP/Lateral Assessment of the Lumbar Spine Density (L1, L2, L3 and L4); Femur Density Assessment (femoral neck, Ward's Triangle, trochanteric region, inter-trochanteric region, and total region); Forearm; and Body Composition Assessment (total body skeletal density, fat and lean).

The **Oral Health Examination** includes examination of the head and neck, oral mucous membranes. Record of restorative appliances, as well as coronal and root caries, and missing teeth are done. Measurements include: plaque assessment, gingival assessment, calculus index, pocket depth measurement, attachment level. Oral radiographs include periapical x-rays for alveolar crestal height (ACH), and mandibular basal bone mineral density (MBMD). Radiographs are taken using a standardized techniques and measured using a computer-assisted technique using a method, training and calibration procedure developed by Dr. Hausmann and successfully applied locally. Samples of saliva, plaque and blood are collected and frozen.

Results and Discussion:

Analysis of study data and report of results will not be available until year-4 when data collection is complete. However outlined below is a detailed report of our recruitment experience as of the end of year-2. As of 09/15/98 a total 860 (46 recent) letters have been sent to WHI OS participants. Of these, 473 women have completed participation in this study. In addition 133 women are either scheduled to participate, temporarily ineligible but willing, or willing but needing to reschedule. A total of 71 have been uninterested and 66 ineligible for participation. Based on this success, we should meet or exceed our recruitment goal of 1300 enrollees. Further detail on recruitment is presented below.

Recruitment Summary as of 09/15/98

WHI OS Participants Contacted:

860 Total letters sent as of 09/15/98
-46 Recent letters (mailed on 09/14/98) therefore no response yet
814 Letters used for percentages below

Visits Completed, Willing and Eligible:

473 Visits completed (58% of 814)
39 Appointments scheduled
52 Temporarily ineligible but interested (i.e. recent contrast agent, out of town)
42 Need to reschedule due to cancellation
606 Total willing, eligible and likely to participate (74% of 814)

No Contact, Ineligible, Not Interested:

41 No contact/no response
1 Mail not forwardable
1 Moved out of area
13 Undecided
71 Not interested
15 Deceased
66 Ineligible:
- 43 Edentulous/less than 6 teeth
- 6 Fear of x-rays
- 6 Bilateral hip replacement
- 5 Cancer/Disease
- 2 Report being ill
- 2 Positional vertigo
- 1 Not ambulatory
- 1 In nursing home

152 Total ineligible, unwilling or unable to contact (19% of 814)

Recommendations In Relation To The Outline Of Work:

The Timeline/Statement of Work from our proposal/funding application is presented below. For each of the tasks, a description of what has been completed and the relation to the timeline are described. In general, tasks have initiated and/or completed within the proposed time frame. When the time frame differs, an explanation is provided.

Proposed Timeline From Application:

Task 1: **Months 1-3+:** Hire personnel, complete training and certification (Nurse mgr, DXA tech, Dental Fellow, clerk, data mgr.)

We have hired, trained and certified a number of staff and key personnel. The personnel who have been employed during year-2 of this grant include:

Staff Name	Position
Jean Wactawski-Wende, PhD	Principal Investigator
Robert Genco, DDS PhD	Co-Investigator
Sara Grossi, DDS MS	Co-Investigator
Ernest Hausmann, DMD PhD	Co-Investigator
Myroslaw Hreshchyshyn, MD	Co-Investigator
Maurizio Trevisan, MD MS	Co-Investigator
Cheryl Klemenz	Project Manager/Data Manager
Laurie Barrick*	DXA Technician
Dorothy Wright	Secretary/Data Clerk
Sharon Chory	Data Entry
June Markello	Dental Hygienist/Assistant
Bridget McGinness	Project Aide (Summer 1998)

*Position funded through Gebby Foundation grant.

In addition to the investigators and staff employed on the grant, we have had a number of *in kind* contributions of staff from the University at Buffalo:

Staff Name	Position
Juan Loza, DDS PhD	Scientific Support
Mine Tezal, DDS MS	Dentist/Examiner
Millicent Schmidt, DDS	Dentist/Examiner
Jim Katancik, DDS PhD	Dentist/Examiner
Michael Lynch, DMD	Dentist/examiner
Jeffrey Rogers, DDS	Dentist/examiner
Linda Roth	Dental Hygienist/Assistant
Patricia Gill	Dental Hygienist/Assistant
Jan Benedek	Dental Hygienist/Assistant
Steve Lancaster	Dental Hygienist/Assistant
Robert Dunford, MS	Dental Data Manager

All staff have been trained to conduct their respective duties and certified. All dental training and certification has by done by Dr. Sara Grossi, study co-investigator. Laurie Barrick is a NYS Licensed X-Ray Technician. She was sent to Hologic to receive manufacturer training and is locally trained and monitored by Drs. Wactawski-Wende and Hreshchyshyn. Cheryl Klemenz serves as Project Manager and oversees the daily operation of the study and staff.

All investigators are actively involved in the project activities and meet regularly to discuss all aspects of the study. Investigators include Drs. Wactawski-Wende, Genco, Grossi, Hausmann, Hreshchyshyn and Trevisan.

Task 2: **Months 1-3:** Identify OS participants from WHI database
Link study files to WHI OS participant files

The roster of all Observational Study participants from the WHI was extracted and a participant database was created for this study. This database is being used for all study mailings and contacts. It is updated periodically from the WHI roster to insure accuracy of address and other contact information. A separate data file has been completed to enter all clinical and questionnaire information we collect during the study. The data files are separate from the files which include patient identifiers for confidentiality reasons, linked by an study identification number.

Task 3: **Months 2-4:** Finalize study questionnaire; pilot test questionnaire

The questionnaires have been completed and approved for use by both our local IRB and the Army IRB. The questionnaires are completed by all participants. The information included on these questionnaires are supplemental to that already collected as part of WHI. Copies of these questionnaires can be found in the Appendix.

Task 4: **Months 4-6:** Preparation of initial sample mailing and contact to test contact procedures

Conduct pilot testing of examination procedures on sample of OS participants

Create computerized data files for entry of questionnaires and non-computerized clinical data

As reported in the last annual report, sample mailings were conducted in a pilot population of 80 subjects. The contact letter, screening questionnaires and consent were approved by the Army Human Use and University at Buffalo IRB. They are being used. The pilot process was very useful in determining timing of appointments and logistics for conducting the study. It was also useful for training and certification of staff. The data entry files have been created and data entry is ongoing.

Task 5: **Months 6-7:** Evaluate and revise procedures based on pilot sample

Procedures have been evaluated and some revisions of the original grant were requested and received which have been implemented (i.e. blood, saliva and plaque collection; forearm scan). The pilot was very useful in helping to evaluate procedures within the osteo/dental clinic setting.

Task 6: **Months 7-40:** Begin weekly mailings to approximately 70 women

Weekly mailings have begun. As of 09/15/98, a total of 860 OS participants were contacted by mail. Details of the results of mailings are presented in "Results and Discussion". Our mailings are ongoing into year-4 of the study.

Task 7: **Months 8-40:** Conduct eligibility screens on interested participants

Obtain informed consent

Conduct DXA/Dental evaluations and have participants complete study questionnaires

Continue quality control procedures throughout study to ensure quality of examiners

In an ongoing fashion we have been completing eligibility screen, scheduling appointments for those interested and eligible, obtaining informed consent, conducting both the DXA and dental examinations, collecting questionnaire information, and continuing quality control of all examining staff. As of 09/15/98 a total of 473 women have completed participation in the study. Task 7 activities will continue into year-4 of the study.

Task 8: **Months 9-42:** Entry of questionnaire data and verification

Data management of computerized files

Entry and verification of the study data has been ongoing. The computerized files for data entry have been created and are in use. The data from both the DXA scan and Dental exam are directly entered at time of visit and will be merged with questionnaire and WHI data when analysis is started. Back up copies of all data files are kept daily.

Task 9: **Months 40-48:** Begin preliminary data analysis; conduct multivariate analysis

Begin manuscript preparation

Inform participants of initial findings of the study

These activities will be conducted in year 4 of this study

CONCLUSIONS

Results of this research will not be available until the last year of funding, however the importance and implications of this study are many. The proposed study has great practical significance since if oral bone loss is a predictor of skeletal bone loss, those women who are detected on dental exam to have oral bone loss could be targeted to have further evaluation of skeletal bone density to determine their risk of osteoporosis. These women could then be targeted for interventions which could prevent progression and/or future fracture. Conversely, women with severe skeletal osteopenia may need to be evaluated for risk of oral bone loss, in order to target interventions to prevent progression and subsequent tooth loss. This study potentially provides a new approach for screening for women at risk for osteoporosis.

REFERENCES

1. Wactawski-Wende J, Grossi SG, Trevisan M, Genco RJ, Tezal M, Dunford RG, Ho AW, Hausmann E, and Hreshchyshyn MM. The Role of Osteopenia in Oral Bone Loss and Periodontal Disease. *J Periodontol* 1996; 67:1076-1084.

APPENDIX

Study Questionnaires

Osteo Telephone Screen

Name _____ _____ _____ _____
Title First MI Last

Address _____

_____

Phone _____(H) _____(W)

Have you ever had any of the following:

_____ **Cancer:** _____(Type)
___/___ Month and Year of diagnosis
_____ Evidence of cancer in last year
_____ Did the cancer ever spread to the **bone**
_____ Therapy now: _____
_____ **Liver disorder**
_____ Cirrhosis
_____ Hepatitis B
_____ Other:_____
_____ **Bowel** or colon surgically removed
_____ **Organ transplant:** _____ ___/___
_____ Either or both **hips replaced**
_____ **Paget's** disease or any **other bone disease**

Do you have at least **six** of your **natural teeth**? _____(Y)

When was the last time you had a **full set of dental x-rays** taken? _____

Have you been **hospitalized overnight** for a major event in the **past 3 months**? _____(N)

Have you had any **gum surgery** or therapy in the **past 3 months**? _____(N)

Are you currently in any type of study where you are unaware of the treatment or intervention you are receiving?
_____(N) If yes, specify_____

Are there any reasons that may make it difficult for you to complete an accurate history about yourself?
_____(N)

Will you be able to get to the clinic? _____(Y)

Are you willing to have **low dose x-rays** done for both the dental/bone density sections of the study?_____(Y)

Is there any chance that you may be **pregnant**? _____(N)

Do you take any type of blood thinner? _____(N) ***If yes***, which one and what dose _____/_____

Do you know what your Post-Thrombin Time (PTT) or what your INR is? _____

Has your physician advised you to take **antibiotics** prior to any dental work because of an artificial joint or because you have a heart condition that requires pre-medication to prevent Subacute Bacterial Endocarditis? _____ *(If yes, continue on)*

Do you have your **own supply** of antibiotics to take? _____
Do we need to **call in a script** for you? _____ Pharmacy _____phone #_____
Usual meds_____ Dose_____ Any allergies_____

Date: _____ **Initial:** _____

Osteo Visit Screen

Name_____ ID#_____ Date: ___/___/___

Height: ____'____" Weight: _____lbs. SS#_____

Y **N** Have you had any **gum surgery** or therapy since we scheduled this visit?

Y **N** Have you been **hospitalized overnight** for major surgery or event since we scheduled this visit?

Y **N** Have you had any tests which used **contrast agents** in the past month?

Y N Has your physician advised you to take **antibiotics** prior to any dental work because of an artificial joint or because you have heart condition that requires pre-medication to prevent Subacute Bacterial Endocarditis (infection of the heart)? [if yes, go to next question, if no, skip next question and go on]

Y N Have you taken your own medication or will you need us to supply it? [circle one]
What did you take?_____

Y N Have you had any **changes in your health** since we scheduled this visit?
Specify: _____

Y N Did you take a **calcium pill** this morning?

Do you wear a pacemaker? _____

When did you last eat anything? _____

What **medications** are you currently taking:

Medication	**Dose**	**Reason for taking**

Initials: _____

CURRENT MEDICATIONS

Please list below <u>all</u> of the following:

- **Prescription medications**
- **Over the counter medications you take on a regular basis (4 or more times a month)**
- **Hormone medications**
- **Vitamins and minerals**
- **Laxatives and fiber medications**

Medication	Dose	Reason for taking	How long have you been on?

(Please use the back of this sheet if more room is needed.)

*****Please bring with you to your appointment everything listed above in the original bottles.**

Name _____ Date _____/_____/_____

Fluoride Questionnaire

We are examining your lifelong exposure to certain essential minerals that are normally present in drinking water. In order to enable us to determine your intake of these minerals, please list all the communities in which you have lived (as best as you can remember). Please provide detailed information including the town in which you lived, the zip code and whether your home was on a public water system or well water. Please answer only as it applies to your own case. The various time periods that we are interested in are listed as follows.

TIME PERIOD	COMMUNITY	STREET NAME	ZIP CODE	WATER SOURCE *Please circle source*	ADDITIONAL COMMENTS
Birth to age 5				Public Well Don't know	
Age 6 to 5th grade				Public Well Don't know	
6th grade to 8th grade				Public Well Don't know	
9th grade to 12th grade				Public Well Don't know	

(OVER)

TIME PERIOD (by age only)	COMMUNITY	STREET NAME	ZIP CODE	WATER SOURCE *Please circle source*	ADDITIONAL COMMENTS
Ages 18 to 30				Public Well Don't know	
Ages 31 to 45				Public Well Don't know	
Ages 46 to 60				Public Well Don't know	
Ages 61 to 75				Public Well Don't know	
Age 76 and above				Public Well Don't know	

Additional information:

Did you attend college or technical school? Yes _____ No _____

If yes, what was the name of the college or technical school? _____

What city was the school located in? _____

Did you attend for 9 or 12 months out of the year? 9 months _____ 12 months _____

Did you live in the dormitory? Yes _____ No _____

Did you return home when school was not in session? Yes _____ No _____

Your age when you attended college or technical school (i.e. 18 – 22) _____

Were you ever in the military? Yes _____ No _____

Where were you stationed? _____

Your age(s) when you served in the military (i.e. 18 – 22) _____

Additional Comments:

_____

_____

_____

_____

_____

Health History Questionnaire

Name: _____

Part I. Family History

We can learn about risks of disease by asking women what diseases have run in their families. This section is asking for information about your full-blooded relatives only. You do not need to think about half-sisters and half-brothers or relatives who are related to you by marriage or adoption. Full-blooded sisters and brothers are those who had the same two parents as you. If you are adopted or are not sure about some relatives' health history, please include any family history that you know about.

Ethnic Mix:

List the nationalities/ethnic mix of your parents:

Mother:_____ _____ _____ _____

Father: _____ _____ _____ _____

Siblings (List all brother and sisters, both living and deceased):

Please circle relationship	**Year of Birth**	**Living? Yes or No**	**If dead, *AGE* at death**	**If dead, *cause* of death**	**Broken bone after age 40?**		**Ever diagnosed with osteoporosis?**	
					Age	**Bone(s)**	**How?**	**Age?**
Mother								
Father								
1. Brother / Sister								
2. Brother / Sister								
3. Brother / Sister								
4. Brother / Sister								
5. Brother / Sister								
6. Brother / Sister								
7. Brother / Sister								

***Note: Use back of page if necessary**

List ALL family members (blood relatives) known or suspected to have **osteoporosis** (specify relatives and relation to you -- e.g. maternal aunt, paternal grandfather, daughter):

Relative	**Maternal or Paternal**	**How diagnosed?**	**Age**	**Specify any other bone diseases**

***Note: Use back of page if necessary**

Part II. Your Health History

Have *you* ever been diagnosed with osteoporosis? ____Yes ___No

If yes, age at first diagnosis _____

How were you diagnosed (check all that apply):

_____Fracture/Broken bone (over the age of 40)

_____Bone density test

Specify type of test: _____

Where was test performed: _____

_____Marked decrease in height

If loss of height, how much loss?_____inches

_____Hump of back or spine

_____Other diagnosis (specify) _____

_____

_____

Your Fracture history:

Bone Broken (Specify)	Age at Fracture	How did it happen?	How was it treated?

***Note: Use back of page if necessary**

Which is your dominant hand? _____Right _____Left

Have you been diagnosed and/or treated by a physician for any of the following (*check all that apply*) and also fill in the age when you were first diagnosed and/or treated.

Yes(√)	Age		Yes (√)	Age	
_____	____	Kidney/Renal problems	_____	____	Hypertension/High blood pressure
_____	____	Parathyroid disease	_____	____	Heart disease
_____	____	Thyroid disease	_____	____	Diabetes
_____	____	Pituitary gland problem	_____	____	Pancreatic disorder
_____	____	Adrenal gland problem	_____	____	Gastric/Stomach/Intestinal/Bowel problem
_____	____	Ovary problem	_____	____	Depression
_____	____	Pelvic Inflammatory disease	_____	____	Other psychiatric disorder
_____	____	Endometriosis	_____	____	Neurologic condition
_____	____	Osteoarthritis	_____	____	Autoimmune disease
_____	____	Rheumatoid arthritis	_____	____	Bone disease other than osteoporosis

If you have checked any of the conditions on the previous page, please specify details including type of problem and treatment (if any):

_____

_____

_____

_____

List any other problems treated by a physician present or past:

_____

_____

_____

_____

Part III.

For the following SIGNS and SYMPTOMS circle YES or NO if:

NOW - You have the sign or symptom now
PAST - You had the sign or symptom in the past

	NOW		PAST	
1. Significant Weight Problem	Yes	No	Yes	No
2. Excessive Thirst	Yes	No	Yes	No
3. Low Blood Sugar	Yes	No	Yes	No
4. Moles that have Changed in Color and Size	Yes	No	Yes	No
5. Swelling in Neck, Armpit or Groin	Yes	No	Yes	No
6. Pain or Tightness in Chest	Yes	No	Yes	No
7. Shortness of Breath	Yes	No	Yes	No
8. Vomiting	Yes	No	Yes	No
9. Seizures or Epilepsy	Yes	No	Yes	No
10. Persistent or Recurring Numbness of Hands or Feet	Yes	No	Yes	No
11. Persistent or Recurrent Sinus Infection	Yes	No	Yes	No

For the following DISEASES/CONDITIONS circle YES or NO if:

	NOW		PAST	
1. Rheumatic Fever or Rheumatic Heart Disease	Yes	No	Yes	No
2. Congenital Heart Lesions	Yes	No	Yes	No
3. Heart Murmur	Yes	No	Yes	No
4. Mitral Valve Prolapse	Yes	No	Yes	No
5. Arteriosclerosis	Yes	No	Yes	No
6. Allergies (specify _____)	Yes	No	Yes	No
7. Hives or Skin Rash	Yes	No	Yes	No
8. Gout	Yes	No	Yes	No
9. Tuberculosis	Yes	No	Yes	No
10. Mononucleosis	Yes	No	Yes	No
11. Malaria	Yes	No	Yes	No
12. Venereal Disease	Yes	No	Yes	No
13. Anemia or other Blood Disorder	Yes	No	Yes	No
14. Organ Transplant	Yes	No	Yes	No

For the following MEDICATIONS/THERAPIES circle YES or NO if:

	NOW		PAST		Total # months taken	Last taken (month/year)
1. Radiation Therapy	Yes	No	Yes	No	_____	____/____
2. Antibiotics (Penicillin, tetracycline, sulfa, etc.)	Yes	No	Yes	No	_____	____/____
3. Anticoagulants (Blood Thinners)	Yes	No	Yes	No	_____	____/____
4. Diuretics	Yes	No	Yes	No	_____	____/____
5. Cortisone/Prednisone (Steroids)	Yes	No	Yes	No	_____	____/____
6. Antidepressives	Yes	No	Yes	No	_____	____/____
7. Tranquilizers	Yes	No	Yes	No	_____	____/____
8. Digitalis or Drugs for Heart Trouble	Yes	No	Yes	No	_____	____/____
9. Anticholesterol Pills	Yes	No	Yes	No	_____	____/____
10. Antihistamines	Yes	No	Yes	No	_____	____/____
11. Thyroid Pills	Yes	No	Yes	No	_____	____/____
12. Antinausea Pills	Yes	No	Yes	No	_____	____/____
13. Antispasmodics	Yes	No	Yes	No	_____	____/____

	NOW		PAST			
14. Appetite Suppressants	Yes	No	Yes	No	_____	____/____
15. Wear Pace-Maker	Yes	No	Yes	No	_____	____/____
16. Parathyroid Hormone	Yes	No	Yes	No	_____	____/____
17. Growth Hormone	Yes	No	Yes	No	_____	____/____

LIFETIME HORMONAL MEDICATION - For the following MEDICATIONS/THERAPIES circle YES or NO for past and present:

	NOW		PAST		Total # months taken	Last taken (month/year)
1. Birth Control Pills	Yes	No	Yes	No	_____	____/____
2. Estrogen	Yes	No	Yes	No	_____	____/____
3. Progesterone	Yes	No	Yes	No	_____	____/____
4. DES (diethylstilbestrol)	Yes	No	Yes	No	_____	____/____
5. Depo-Provera	Yes	No	Yes	No	_____	____/____
6. Testosterone	Yes	No	Yes	No	_____	____/____
7. Other hormonal therapy (specify _____)	Yes	No	Yes	No	_____	____/____
8. Non-prescription (e.g. teas, herbs) (specify _____)	Yes	No	Yes	No	_____	____/____

Are you allergic or have you reacted adversely to the following: (Please circle Yes or No.)

1. Local Anesthetics	YES	NO
2. Penicillin or other Antibiotics	YES	NO
3. Sulfa Drugs	YES	NO
4. Barbiturates, Sedatives or Sleeping Pills	YES	NO
5. Aspirin	YES	NO
6. Iodine	YES	NO
7. Codeine or other Narcotics	YES	NO
8. Other	YES	NO

Specify _____

Do you have any symptoms related to menopause (change of life)? YES NO

If yes, which of the following do you have now or have you had in the past (Please check which ones.)

	PAST	NOW
Hot flashes	Yes No	Yes No
Depression	Yes No	Yes No
Sleep disturbance	Yes No	Yes No
Bone pains	Yes No	Yes No

Other, please specify _____

These next questions are about your sleep habits. Please mark <u>one</u> of the answers for each of the following questions. Pick the answer that best describes how often you experienced the situation in the <u>past 4 weeks</u>.

1 = No, not in past 4 weeks 2 = Yes, less than once a week 3 = Yes, 1 or 2 times a week
4 = Yes, 3 or 4 times a week 5 = Yes, 5 or more times a week

1.	Did you take any kind of medication or alcohol at bedtime to help you sleep?	1	2	3	4	5
2.	Did you fall asleep during quiet activities like reading, watching TV, or riding in a car?	1	2	3	4	5
3.	Did you nap during the day?	1	2	3	4	5
4.	Did you have trouble falling asleep?	1	2	3	4	5
5.	Did you wake up several times at night?	1	2	3	4	5
6.	Did you wake up earlier than you planned to?	1	2	3	4	5
7.	Did you have trouble getting back to sleep after you woke up too early?	1	2	3	4	5
8.	Did you snore? (If you do not know if you snore put an **X** in this box ☐)	1	2	3	4	5

9. Overall, was your typical night's sleep during the past 4 weeks:
   a.) Very sound or restful
   b.) Sound or restful
   c.) Average quality
   d.) Restless
   e.) Very restless

10. About how many hours of sleep did you get on a typical night during the past 4 weeks?
   a.) 5 or less hours
   b.) 6 hours
   c.) 7 hours
   d.) 8 hours
   e.) 9 hours
   f.) 10 or more hours

Many women report that they leak urine (or pee). The next questions are about problems you may have had with leaking urine.

1. Have you ever leaked even a very small amount of urine involuntarily and you couldn't control it? **Yes No**
   (If you answered no please skip the rest of this section and go on to Part IV.)

2. How often does this leaking urine occur?
   a.) Not once during the past year
   b.) Less than once a month
   c.) More than once a month but less than once a week
   d.) One or more times a week but less than every day
   e.) Daily

3. When do you usually leak urine? (Mark all that apply.)
   a.) No longer leak urine
   b.) When I cough, laugh, sneeze, lift, stand up, or exercise
   c.) When I feel the need to urinate and can't get to a toilet fast enough
   d.) When I am sleeping
   e.) Other, please describe _____

(If you answered "a. no longer leak urine," please skip the rest of this section and go on to Part IV.)

4. How much urine do you usually lose when it leaks? (Mark one answer only.)
   a.) None
   b.) Barely noticeable on underpants
   c.) Soaked underpants
   d.) Soaked through to outer clothing

5. What protection do you wear in case you leak urine? (Mark all that apply.)
   a.) None
   b.) Mini-pad, tissue or paper towel
   c.) Menstrual pad or shield
   d.) Diaper, towel, Attends, Depends

6. How often does the leakage of urine limit your daily activities? (Mark one answer only.)
   a.) Never
   b.) Almost never
   c.) Sometimes
   d.) Fairly often
   e.) Very often

7. How much does the leakage of urine bother or disturb you? (Mark one answer only.)
   a.) Not at all disturbing
   b.) A little disturbing
   c.) Somewhat disturbing
   d.) Very disturbing
   e.) Extremely disturbing

Part IV. Dental Questions

My last dental examination was on: _____ _____
month year

My last dental cleaning was on: _____ _____
month year

For the following items check the appropriate response:

1. How often do you brush your teeth?
   - Not Everyday _____
   - Once a Day _____
   - Twice a Day _____
   - More than Twice a Day _____

2. How often do you floss your teeth?
   - Not Every Week _____
   - Once a Week _____
   - More than Once a Week _____
   - Everyday _____

3. Do you brush your tongue?
   - Yes _____
   - No _____

4. How often do you go to the dentist?
   - More than Once a Year _____
   - Once a Year _____
   - Only with a dental problem _____
   - Never _____

5. How satisfied are you with the appearance of your teeth?
   - Not at all _____
   - Slightly _____
   - Somewhat _____
   - Moderately _____
   - Very Satisfied _____

6. How satisfied are you with your ability to chew food?
   - Not at All _____
   - Slightly _____
   - Somewhat _____
   - Moderately _____
   - Very Satisfied _____

7. How satisfied are you with your breath?
   - Not at All _____
   - Slightly _____
   - Somewhat _____
   - Moderately _____
   - Very Satisfied _____

For the following ORAL CONDITIONS circle YES or NO if:
NOW - You have the condition now
PAST - You had the condition in the past

	NOW		PAST	
1. Tooth ache	Yes	No	Yes	No
2. Sore or Swollen Gums	Yes	No	Yes	No
3. Bleeding Gums	Yes	No	Yes	No
4. Sore or Sensitive Tongue	Yes	No	Yes	No
5. Enlarged Tonsils	Yes	No	Yes	No
6. Cold Sores	Yes	No	Yes	No
7. Teeth sensitive to cold or heat	Yes	No	Yes	No
8. Gum boil (abscess)	Yes	No	Yes	No

For the following ORAL PROCEDURES circle YES or NO if:
NOW - You are being treated/having now
PAST - You were treated/had in the past

	NOW		PAST	
1. Gum Surgery (for Gum Disease)	Yes	No	Yes	No
2. Tooth Cleaning (scaling for Gum Disease)	Yes	No	Yes	No
3. Crowned Teeth (caps) and /or Bridges	Yes	No	Yes	No
4. Wear Removable Partial Dentures/Appliances	Yes	No	Yes	No
5. Surgery for a Tumor or other Condition of your Mouth or Lips	Yes	No	Yes	No
6. X-ray Treatment for a Tumor or other Condition of your Mouth or Lips	Yes	No	Yes	No

Other than your wisdom teeth, were any of your teeth extracted because of:

1. Gum disease	Yes	No
2. Cavities	Yes	No
3. Abnormal position	Yes	No
4. Other	Yes	No

Explain: _____

Part V.

For the following questions check/circle the appropriate responses:

1. Do you consider your appetite at present to be:
   Good _____
   Fair _____
   Poor _____

   If your appetite is **fair or poor** how long has it been that way?
   For the last six months _____ Longer than six months _____

2. Do you have any food allergies?
   Yes _____ No _____

3. Do you follow a special diet?
   No _____

   Yes _____ ⟶ No meat _____
   Total vegetarian _____
   Salt-Free _____
   Kosher _____
   Weight reducing _____
   Other: _____

   If yes, who prescribed this diet?
   Self _____
   Dentist _____
   Physician _____
   Other _____

Do you use or have you used any of the following tobacco products?

	NOW		PAST	
Pipe	Yes	No	Yes	No
Cigars	Yes	No	Yes	No
Smokeless tobacco (snuff)	Yes	No	Yes	No
Chewing tobacco	Yes	No	Yes	No
Cigarettes	Yes	No	Yes	No

How many years have/had other members of your household smoked cigarettes, cigars or pipe in your presence?___

If you smoke ***cigarettes*** **now** or have smoked them in the **past** please complete the following:

What age did you start smoking cigarettes? _____

How many packs per day do you/did you smoke? _____

What has been the most packs per day that you have smoked? _____

If you have quit smoking, at what age did you do so? _____

Part VI. **Alcohol Consumption**

Answer the following questions about your alcohol consumption over the past 12 months.

A. How often do you usually drink ***wine***? (Circle one)

1. 3 or more times a day.
2. 2 times a day.
3. about once a day.
4. 3 or 4 times a week.
5. 1 or 2 times a week.
6. 2 or 3 times a month.
7. about once a month.
8. less than once a month, but at least once over the past 12 months.
9. not sure or don't know
10. never in the past 12 months

B. When you drink ***wine***, how many 4 oz. wine glasses do you usually have at one time, on the average? (Circle one)

1. 12 or more.
2. 10 - 11.
3. 8 - 9.
4. 6 - 7.
5. 4 - 5.
6. 1 - 3.

C. How often do you usually drink ***beer***? (Circle one)

1. 3 or more times a day.
2. 2 times a day.
3. about once a day.
4. 3 or 4 times a week.
5. 1 or 2 times a week.
6. 2 or 3 times a month.
7. about once a month.
8. less than once a month, but at least once over the past 12 months.
9. not sure or don't know
10. never in the past 12 months

D. When you drink ***beer***, how many 12 oz. cans or bottles do you usually have at one time, on the average? (Circle one)

1. 12 or more.
2. 10 - 11.
3. 8 - 9.
4. 6 - 7.
5. 4 - 5.
6. 1 - 3.

E. How often do you usually have a drink of ***liquor*** (whiskey, vodka, gin, rum, mixed drinks, and so forth)?
1. 3 or more times a day.
2. 2 times a day.
3. about once a day.
4. 3 or 4 times a week.
5. 1 or 2 times a week.
6. 2 or 3 times a month.
7. about once a month.
8. less than once a month, but at least once in the past 12 months.
9. not sure or don't know
10. never in the past 12 months

F. When you drink ***liquor***, how many one and a half oz. shots or mixed drinks do you have at one time, on the average?
1. 12 or more
2. 10 - 11.
3. 8 - 9.
4. 6 - 7.
5. 4 - 5.
6. 1 - 3.

For the next few questions, assume that one drink is one can of beer, one 4 oz. glass of wine or one shot of liquor.

G. During the past 12 months, how often have you had any kind of alcoholic beverage?
1. 3 or more times a day.
2. 2 times a day.
3. about once a day.
4. 3 or 4 times a week.
5. 1 or 2 times a week.
6. 2 or 3 times a month.
7. about once a month.
8. less than once a month, but at least once in the past 12 months.
9. not sure or don't know
10. never in the past 12 months

H. Still thinking about the past 12 months, about how many drinks of alcoholic beverages would you have at one time?
1. 12 or more
2. 10 - 11.
3. 8 - 9.
4. 6 - 7.
5. 4 - 5.
6. 1 - 3.

I. Over the last 10 years, have your drinking habits changed?
0. no
1. yes
2. Over the past ten years, I have not had a drink.

If you answered "yes" please go on to question J. If you answered something else please go on to "Caffeine Consumption".

J. Have your drinking habits....
1. decreased
2. increased
3. stayed the same
4. my drinking of alcoholic beverages has stopped
5. other, please specify _____

_____

K. If your drinking habits have changed over the last 10 years, was it because you were advised to do so by a physician?
1. yes
2. no, I decided to do so on my own

L. When did your drinking habits change?
1. 1 year ago or less.
2. 1 year ago to less than 3 years ago.
3. 3 years ago to less than 5 years ago.
4. 5 years ago to less than 7 years ago.
5. 7 years ago to less than 9 years ago.
6. 9 years ago or more.

Caffeine Consumption

	NOW		**PAST**		**# cups/day (8 ounces = 1 cup)**
Coffee	Yes	No	Yes	No	_____
Tea	Yes	No	Yes	No	_____
Pop/soda	Yes	No	Yes	No	_____
Other, please specify_____	Yes	No	Yes	No	_____

Have you ever been exposed to the following occupational hazards?

	NOW		**PAST**	
Chemicals	Yes	No	Yes	No
Asbestos	Yes	No	Yes	No
Radiation	Yes	No	Yes	No
Other	Yes	No	Yes	No

Describe type and source of exposure _____

_____

How many years have you been exposed _____

Name _____ **Date** _____

This form has questions about your behavior, feelings, and experiences. Please answer each question as honestly as you can. No one will see your answers except for the scientists and staff at the clinic. Your answers will be kept secret and will never be put with your name in a report. Please answer using your first thoughts about each question. Do not go back later to "figure out" answers. Your answers will help us to understand how behaviors, thoughts and feelings affect the health of women like you. Thank you for your help.

A. Below are conditions people sometimes have to work with in their jobs. CIRCLE THE NUMBER THAT INDICATES HOW MUCH OF THE TIME YOU HAVE THESE CONDITIONS AT YOUR JOB.

1 = Almost always 2 = Much of the time 3 = Once in a while 4 = Never or almost never

1. Do you have more work than you can handle?	1	2	3	4
2. Do you have a lot of noise on the job?	1	2	3	4
3. Do you work in a lot of dirt or dust?	1	2	3	4
4. Are you in danger of illness or injury on the job?	1	2	3	4
5. Do you do the same thing over and over again?	1	2	3	4
6. Are you under pressure to keep up with new ways of doing things?	1	2	3	4
7. Do you work too many hours?	1	2	3	4

B. Below are statements about different benefits people have with theirs jobs. CIRCLE THE NUMBER THAT INDICATES HOW MUCH YOU AGREE OR DISAGREE WITH EACH STATEMENT.

1 = Strongly agree 2 = Somewhat agree 3 = Somewhat disagree 4 = Strongly disagree

1. The income I earn is just about right for the job I do.	1	2	3	4
2. I can count on a steady income.	1	2	3	4
3. My chances for increased earnings in the next year or so are good.	1	2	3	4
4. The work I'm doing now is preparing me for a better work situation.	1	2	3	4
5. My work has good fringe benefits such as sick pay and retirement.	1	2	3	4
6. There is always a chance I may be out of a job.	1	2	3	4

C. Below is a list of different things that sometimes happen to people on their jobs. CIRCLE THE NUMBER THAT INDICATES HOW OFTEN EACH ONE HAPPENS TO YOU.

1 = Never 2 = Once in a while 3 = Fairly often 4 = Very often

1. Do people act towards you as if you are a person without real feelings?	1	2	3	4
2. Do people come to you for your opinions about how the work should be done?	1	2	3	4
3. Do you have to do tasks that no one else wants to do?	1	2	3	4
4. Do people treat you in an unfriendly way?	1	2	3	4
5. Are you told that your doing a good job?	1	2	3	4
6. Are you treated unfairly by another person?	1	2	3	4

D. Below are some questions about finances. CIRCLE THE NUMBER THAT BEST DESCRIBES YOUR FINANCIAL SITUATION.

	YES	NO
1. At the present time are you able to afford a home that is large enough?	1	2
2. At the present time are you able to afford furniture or household equipment that needs to be replaced?	1	2
3. At the present time are you able to afford the kind of car you need?	1	2

4. How much difficulty do you have in meeting the monthly payments of (you/your family's) bills? Do you have:

   A great deal of difficulty.....1

   Some difficulty.....2

   Only a little difficulty.....3

   No difficulty at all.....4

5. In general, how do your (you/your family's) finances usually work out at the end of the month? Do you find that you usually end up with:

   Some money left over.....1

   Just enough to make ends meet.....2

   Not enough to make ends meet.....3

1 = Never 2 = Once in a while 3 = Fairly often 4 = Very often

6. How often does it happen that you don't have enough money to afford the kind of food you/your family should have?	1	2	3	4
7. How often does it happen that you don't have enough money to afford the kind of medical care you/your family should have?	1	2	3	4
8. How often does it happen that you don't have enough money to afford the kind of clothing you/your family want(s)?	1	2	3	4
9. How often does it happen that you don't have enough money to afford the leisure activities that you/your family want(s)?	1	2	3	4

E. **Below are some statements about relationships with a spouse or partner. <u>CIRCLE</u> THE NUMBER THAT INDICATES HOW MUCH YOU AGREE OR DISAGREE WITH EACH STATEMENT FOR YOUR EXPERIENCE WITH YOUR SPOUSE/PARTNER.** ***(If you are single go to Section F).***

1 = Strongly agree 2 = Somewhat agree 3 = Somewhat disagree 4 = Strongly disagree

1. My spouse/partner insists on having his/her own way.	1	2	3	4
2. My spouse/partner usually expects more from me than he/she is willing to give.	1	2	3	4
3. My spouse/partner usually acts as if he/she were the only important person in the family.	1	2	3	4
4. Generally, I give in more to my spouse/partner's wishes than he/she gives to mine.	1	2	3	4
5. My spouse/partner seems to bring out the best in me.	1	2	3	4
6. My spouse/partner appreciates me just as I am.	1	2	3	4
7. My marriage doesn't give me enough opportunity to become the sort of person I'd like to be.	1	2	3	4
8. I cannot completely be myself around my spouse/partner.	1	2	3	4

1 = Strongly agree 2 = Somewhat agree 3 = Somewhat disagree 4 = Strongly disagree

9. My spouse/partner is someone I can really talk with about things that are important to me.	1	2	3	4
10. My spouse/partner is someone who is affectionate toward me.	1	2	3	4
11. My spouse/partner is someone who is a good sexual partner.	1	2	3	4
12. My spouse/partner is someone who spends money wisely.	1	2	3	4
13. My spouse/partner is someone who is a good wage earner.	1	2	3	4
14. My spouse/partner is someone who appreciates the job I do as a wage earner.	1	2	3	4
15. My spouse/partner is someone who is a good housekeeper.	1	2	3	4
16. My spouse/partner is someone who appreciates the job I do as a housekeeper.	1	2	3	4

F. **Below are some situations single people find themselves in. CIRCLE THE NUMBER THAT INDICATES HOW OFTEN YOU FIND YOURSELF IN EACH SITUATION LISTED. (Answer these questions ONLY if you are not married or have no steady partner).**

1 = Never 2 = Once in a while 3 = Fairly often 4 = Very often

1. Do you feel out of place in a social situation because you are not married?	1	2	3	4
2. Are you without anyone to talk to about yourself?	1	2	3	4
3. Are you without anyone you can share your experiences and feelings with?	1	2	3	4
4. Do you have a chance to have fun?	1	2	3	4
5. Do you stay at home because you are afraid to go out at night?	1	2	3	4
6. Do you wonder if you may not be an interesting person?	1	2	3	4
7. Do you feel that you are not having the kind of sex life you would like?	1	2	3	4

G. Please answer the following two questions as they relate to your children *or* the children you have a major responsibility for.

1. How many children do you have? Females _____ Males _____

2. What are their ages? Females _____ Males _____

_____ _____

_____ _____

_____ _____

_____ _____

H. Below are some experiences parents and caregivers have with their children. <u>CIRCLE</u> THE NUMBER THAT INDICATES HOW OFTEN YOU HAVE THESE EXPERIENCES. (Please answer the following questions if you have children or if you have major responsibility for the care of children.) IF YOU DO NOT HAVE CHILDREN PLEASE GO ON TO SECTION L. If the experience does not apply to you because of your children's age(s), circle the letters NA which means does not apply due to age.

1 = Never 2 = Once in a while 3 = Fairly often 4 = Very often NA = Does not apply due to age

1. You are treated without proper respect.	1	2	3	4	NA
2. Your advice and guidance are ignored.	1	2	3	4	NA
3. You are helped with household chores without asking.	1	2	3	4	NA
4. You are disobeyed.	1	2	3	4	NA

I. How often do you have to give some attention to the correction of:

1 = Never 2 = Once in a while 3 = Fairly often 4 = Very often NA = Does not apply due to age

1. Misbehavior in the house.	1	2	3	4	NA
2. Your child(ren) having the wrong kind of friends.	1	2	3	4	NA
3. Your children failing to get along with others the same age.	1	2	3	4	NA
4. Carelessness about personal appearance.	1	2	3	4	NA
5. Poor school work.	1	2	3	4	NA
6. Poor use of spare time.	1	2	3	4	NA

J. How often do you wonder if your child or children:

1 = Never 2 = Once in a while 3 = Fairly often 4 = Very often NA = Does not apply due to age

1. Are living too much for the present and thinking too little of what lie ahead?	1	2	3	4	NA
2. Are showing too little interest in religion?	1	2	3	4	NA
3. Are not practicing the moral beliefs that are important?	1	2	3	4	NA
4. Might be tempted to try illegal drugs?	1	2	3	4	NA
5. Are not trying hard enough to prepare (herself/himself/themselves) for the life ahead of (her/him/them)?	1	2	3	4	NA
6. Might be using too much alcohol?	1	2	3	4	NA
7. Are not headed for the success you want for her/him/them?	1	2	3	4	NA
8. May not be headed for a good family life?	1	2	3	4	NA
9. Do not take your feelings into consideration?	1	2	3	4	NA
10. Are not very warm or sympathetic toward you?	1	2	3	4	NA
11. Do not pay enough attention to your advice and opinions?	1	2	3	4	NA
12. Are not very aware of your problems?	1	2	3	4	NA
13. Are too dependent on you for guidance and direction?	1	2	3	4	NA
14. Expect you to do too much for them?	1	2	3	4	NA

K. How often does it happen that your child or children:

1 = Never 2 = Once in a while 3 = Fairly often 4 = Very often NA = Does not apply due to age

1. Cry without your knowing why	1	2	3	4	NA
2. Have poor appetites	1	2	3	4	NA
3. Have difficulty sleeping	1	2	3	4	NA
4. Demands too much from you	1	2	3	4	NA

1 = Never 2 = Once in a while 3 = Fairly often 4 = Very often NA = Does not apply due to age

5. Do things slowly for their age	1	2	3	4	NA
6. Do not want as much attention as you want to give them	1	2	3	4	NA
7. Are hard to control	1	2	3	4	NA
8. Do not play well with other children	1	2	3	4	NA
9. Do not interact well with other adults	1	2	3	4	NA

L. Below is a list of problems and complaints that people sometimes have. Please read each one carefully. After you have done so, please CIRCLE one of the numbers to the right that best describes HOW MUCH DISCOMFORT THAT PROBLEM HAS CAUSED YOU DURING THE PAST WEEK INCLUDING TODAY. Mark only one answer and do not skip any items. If you change your mind please erase your first choice carefully.

0 = Not at all 1 = A little bit 2 = Moderately 3 = Quite a bit 4 = Extremely

1. Nervousness or shakiness inside	0	1	2	3	4
2. Faintness or dizziness	0	1	2	3	4
3. The idea that someone else can control your thoughts	0	1	2	3	4
4. Feeling others are to blame for most of your troubles	0	1	2	3	4
5. Trouble remembering things	0	1	2	3	4
6. Feeling easily annoyed or irritated	0	1	2	3	4
7. Pains in heart or chest	0	1	2	3	4
8. Feeling afraid in open spaces	0	1	2	3	4
9. Thoughts of ending your life	0	1	2	3	4
10. Feeling that most people cannot be trusted	0	1	2	3	4
11. Poor appetite	0	1	2	3	4
12. Suddenly scared for no reason	0	1	2	3	4
13. Temper outbursts that you could not control	0	1	2	3	4
14. Feeling lonely even when you are with people	0	1	2	3	4
15. Feeling blocked in getting things done	0	1	2	3	4
16. Feeling lonely	0	1	2	3	4
17. Feeling blue	0	1	2	3	4
18. Feeling no interest in things	0	1	2	3	4

0 = Not at all 1 = A little bit 2 = Moderately 3 = Quite a bit 4 = Extremely

19. Feeling Fearful	0 1 2 3 4
20. Your feelings being easily hurt	0 1 2 3 4
21. Feeling that people are unfriendly or dislike you	0 1 2 3 4
22. Feeling inferior to others	0 1 2 3 4
23. Nausea or upset stomach	0 1 2 3 4
24. Feeling that you are watched or talked about by others	0 1 2 3 4
25. Trouble falling asleep	0 1 2 3 4
26. Having to check and double check what you do	0 1 2 3 4
27. Difficulty making decisions	0 1 2 3 4
28. Feeling afraid to travel on buses, subways or trains	0 1 2 3 4
29. Trouble getting your breath	0 1 2 3 4
30. Hot or cold spells	0 1 2 3 4
31. Having to avoid certain things, places, or activities because they frighten you	0 1 2 3 4
32. Your mind going blank	0 1 2 3 4
33. Numbness or tingling in parts of your body	0 1 2 3 4
34. The idea that you should be punished for your sins	0 1 2 3 4
35. Feeling hopeless about the future	0 1 2 3 4
36. Trouble concentrating	0 1 2 3 4
37. Feeling weak in parts of your body	0 1 2 3 4
38. Feeling tense or keyed up	0 1 2 3 4
39. Thoughts of death or dying	0 1 2 3 4
40. Having urges to beat, injure, or harm someone	0 1 2 3 4
41. Having urges to break or smash things	0 1 2 3 4
42. Feeling very self-conscious with others	0 1 2 3 4

0 = Not at all 1 = A little bit 2 = Moderately 3 = Quite a bit 4 = Extremely

43. Feeling uneasy in crowds	0	1	2	3	4
44. Never feeling close to another person	0	1	2	3	4
45. Spells of terror or panic	0	1	2	3	4
46. Getting into frequent arguments	0	1	2	3	4
47. Feeling nervous when you are left alone	0	1	2	3	4
48. Others not giving you proper credit for your achievements	0	1	2	3	4
49. Feeling so restless you could not sit still	0	1	2	3	4
50. Feelings of worthlessness	0	1	2	3	4
51. Feeling that people will take advantage of you if you let them	0	1	2	3	4
52. Feelings of guilt	0	1	2	3	4
53. The idea that something is wrong with your mind	0	1	2	3	4

PLEASE CONTINUE ON TO NEXT PAGE.

We are interested in how people respond when they confront difficult or stressful events in their lives. There are lots of ways to try to deal with stress. This questionnaire asks you to indicate what **YOU** generally do and feel, when *you* experience stressful events. Obviously, different events bring out somewhat different responses, but think about what you usually do when you are under a lot of stress.

Then respond to each of the following items by **CIRCLING ONE NUMBER ON THE RIGHT-HAND SIDE OF THE PAGE USING THE RESPONSE CHOICES LISTED JUST BELOW**. Please try to respond to each item *separately in your mind from each other item.* Choose your answers thoughtfully, and make your answers as true FOR YOU as you can. Please answer every item. There are no "right" or "wrong" answers, so choose the most accurate answer for **YOU**--not what you think "most people" would say or do. Indicate what **YOU** usually do when **YOU** experience a stressful event.

1 = I usually don't do this at all **2 = I usually do this a little bit**
3 = I usually do this a medium amount **4 = I usually do this alot**

1.	I try to grow as a person as a result of the experience.	1 2 3 4
2.	I turn to work or other substitute activities to take my mind off things.	1 2 3 4
3.	I get upset and let my emotions out.	1 2 3 4
4.	I try to get advice from someone about what to do.	1 2 3 4
5.	I concentrate my efforts on doing something about it.	1 2 3 4
6.	I say to myself "this isn't real."	1 2 3 4
7.	I put my trust in God.	1 2 3 4
8.	I laugh about the situation.	1 2 3 4
9.	I admit to myself that I can't deal with it, and quit trying.	1 2 3 4
10.	I restrain myself from doing anything too quickly.	1 2 3 4
11.	I discuss my feeling with someone.	1 2 3 4
12.	I use alcohol or drugs to make myself feel better.	1 2 3 4
13.	I get used to the idea that it happened.	1 2 3 4
14.	I talk to someone to find out more about the situation.	1 2 3 4
15.	I keep myself from getting distracted by other thoughts or activities.	1 2 3 4

1 = I usually don't do this at all
2 = I usually do this a little bit
3 = I usually do this a medium amount
4 = I usually do this alot

16. I daydream about things other than this.	1 2 3 4
17. I get upset, and am really aware of it.	1 2 3 4
18. I seek God's help.	1 2 3 4
19. I make a plan of action.	1 2 3 4
20. I make jokes about it.	1 2 3 4
21. I accept that this has happened and that it can't be changed.	1 2 3 4
22. I hold off doing anything about it until the situation permits.	1 2 3 4
23. I try to get emotional support from friends or relatives.	1 2 3 4
24. I just give up trying to reach my goal.	1 2 3 4
25. I take additional action to try to get rid of the problem.	1 2 3 4
26. I try to lose myself for a while by drinking alcohol or taking drugs.	1 2 3 4
27. I refuse to believe that it has happened.	1 2 3 4
28. I let my feelings out.	1 2 3 4
29. I try to see it in a different light, to make it seem more positive.	1 2 3 4
30. I talk to someone who could do something concrete about the problem.	1 2 3 4
31. I sleep more than usual.	1 2 3 4
32. I try to come up with a strategy about what to do.	1 2 3 4
33. I focus on dealing with this problem, and if necessary let other things slide a little.	1 2 3 4

1 = I usually don't do this at all **2 = I usually do this a little bit**
3 = I usually do this a medium amount **4 = I usually do this alot**

34. I get sympathy and understanding from someone.	1 2 3 4
35. I drink alcohol or take drugs, in order to think about it less.	1 2 3 4
36. I kid around about it.	1 2 3 4
37. I give up the attempt to get what I want.	1 2 3 4
38. I look for something good in what is happening.	1 2 3 4
39. I think about how I might best handle the problem.	1 2 3 4
40. I pretend that it hasn't really happened.	1 2 3 4
41. I make sure not to make matters worse by acting too soon.	1 2 3 4
42. I try hard to prevent other things from interfering with my efforts at dealing with this.	1 2 3 4
43. I go to movies or watch TV, to think about it less.	1 2 3 4
44. I accept the reality of the fact that it happened.	1 2 3 4
45. I ask people who have had similar experiences what they did.	1 2 3 4
46. I feel a lot of emotional distress and I find myself expressing those feelings a lot.	1 2 3 4
47. I take direct action to get around the problem.	1 2 3 4
48. I try to find comfort in my religion.	1 2 3 4
49. I force myself to wait for the right time to do something.	1 2 3 4
50. I make fun of the situation.	1 2 3 4
51. I reduce the amount of effort I'm putting into solving the problem.	1 2 3 4
52. I talk to someone about how I feel.	1 2 3 4
53. I use alcohol or drugs to help me get through it.	1 2 3 4

1 = I usually don't do this at all **2 = I usually do this a little bit**
3 = I usually do this a medium amount **4 = I usually do this alot**

54. I learn to live with it.	1 2 3 4
55. I put aside other activities in order to concentrate on this.	1 2 3 4
56. I think hard about what steps to take.	1 2 3 4
57. I act as though it hasn't even happened.	1 2 3 4
58. I do what has to be done, one step at a time.	1 2 3 4
59. I learn something from the experience.	1 2 3 4
60. I pray more than usual.	1 2 3 4

THANK YOU FOR COMPLETING THIS FORM.

VOLUNTEER REGISTRY DATA SHEET

THIS FORM IS AFFECTED BY THE PRIVACY ACT OF 1974

1. AUTHORITY: 5 USC 301; 10 USC 1071-1090; 44 USC 3101; EO 9397

2. Principal and Routine Purposes: To document participation in research conducted or sponsored by the U.S. Army Medical Research and Development Command. Personal information will be used for identification and location of participants.

3. Mandatory or Voluntary Disclosure: The furnishing of the SSN is mandatory and necessary to provide identification and to contact you if future information indicates that your health may be adversely affected. Failure to provide the information may preclude your participation in the research study.

PART A-INVESTIGATOR INFORMATION

(To Be Completed By Investigator)

PLEASE PRINT, USING INK OR BALLPOINT PEN

1. Study NR: OS950077 2. Protocol Title: "Risk Factors for Osteoporosis and Oral Bone Loss in Postmenopausal Women"

3. Contractor (Laboratory/Institute Conducting Study): Research Foundation of the State University of New York at Buffalo

4. Study Period: From: 01/9/96 (DA/MO/YR) To: 15/9/00 (DA/MO/YR)

5. Principal/Other Investigator(s) Names(s) — 6. Location/Laboratory

(1) Wactawski-Wende (Last) Jean (First) (MI) — 65 Farber Hall

(2) Grossi Sara — 65 Farber Hall

(3) Trevisan Maurizio — 65 Farber Hall

PART B-VOLUNTEER INFORMATION

(To Be Completed By Volunteer)

PLEASE PRINT, USING INK OR BALLPOINT PEN

7. SSN:____/____/_____ 8. Name: _____ *(Last) (First) (MI)*

9. Sex: M__F__ 10. Date of Birth: __/__/__ 11. *MOS/Job Series:___ 12. *Rank/Grade:____

13. Permanent Home Address (Home of Record) or Study Location Address:

_____
(Street) *(P.O. Box/Apartment No.)*

_____
(City) *(Country)* *(State)* *(Zip Code)*

( ) -
(Perm Home Phone No)

14. *Local Address (If Different From Permanent Address):

_____
(Street) *(P.O. Box/Apartment No.)*

_____
(City) *(Country)* *(State)* *(Zip Code)*

( ) -
(Local Phone No)

15.*Military Unit: _____ Zip Code: _____

Organization: _____ Post: _____ Duty Phone No. ( ) -

PART C-ADDITIONAL INFORMATION

(To Be Completed By Investigator)

PLEASE PRINT, USING INK OR BALLPOINT PEN

16. Location of Study: University at Buffalo, 65 Farber Hall, 3435 Main Street, Buffalo, New York 14214-3000

17. Is Study Completed: Y___ N_X_

Did volunteer finish participation: Y___ N___ If YES, Date finished: ___/___/___ *(DA/MO/YR)*

If NO, Date withdrawn: ___/___/___ *(DA/MO/YR)* Reason withdrawn:

18. Did Any Serious or Unexpected Adverse Incident or Reaction Occur: Y___N___ If YES, Explain:

19.*Volunteer Followup: _____

Purpose: _____

Date: ___/___/___ *(DA/MO/YR)* Was contact made: Y___N___ If No action taken, explain:

20.*Hard Copy Records Retired: Place: _____ File NR: _____

21.*Product Information:

Product: _____

Manufacturer: _____

Lot NR: _____ Expiration Date: _____

NDA NR: _____ IND/IDE NR: _____

*Indicates that item may be left blank if information is unavailable or does not apply.
Entries must be made for all other items.